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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,880

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EXAMINER

ARCHIE, NINA

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,880	<b>Applicant(s)</b> RHEE ET AL.	
	<b>Examiner</b> Nina A. Archie	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/4/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 7 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/2006, 7/19/2007</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Drawings***

2. The drawings in this application have been accepted. No further action by Applicant is required.

### ***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Information Disclosure Statement***

4. The information disclosure statement filed on 7/11/2006, 7/19/2007, and 10/7/2008 has been considered. Initialed copies are enclosed.

### ***Election/Restrictions***

5. Applicant's election with traverse of Group I, (claims 1-3 and 6-7 and further election of SEQ ID NOs: 5 and 6 of claim 3) are acknowledged. The traversal is on the ground(s) that Applicants respectfully disagree with the Office's assertion and submit that the claimed invention shows superior activity over the art.

As shown in Jeong et al., A Bacterial Flagellin, *Vibrio vulnificus* FlaB, Induces Human Dendritic Cell Maturation, *Journal of Bacteriology and Virology* 2005, Vol. 35, Vo. 3, pp. 209- 216 (which is published after the earliest effective filing date of the instant application; a copy is submitted as APPENDIX A), flagellins A, B, C, D, E and F

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of the *Vibrio vulnificus* have TLR-5 agonistic activity. The experimental data, which is submitted as an APPENDIX B, show that the bacterial flagellins of the present invention have a slight protecting effect in the systemic immune system, whereas they have a superior activity in the mucosal immune system (See "Data showing superiority of a flagellin as a mucosal adjuvant"). In the result of the experiment, the intraperitoneally (systemic route) infected mice did not show the effect of protecting against *V. vulnificus* (0% survival) [See FIGS. 1 and 2(a) in Data showing superiority of flagellin as a mucosal adjuvant"], whereas all of the orally (mucosal route) infected mice were completely protected [See FIG. 2(b) in Data showing superiority of a flagellin as a mucosal adjuvant"].

Therefore, Applicants respectfully submit that the special technical feature of the invention defined in the claims exists. This is not found persuasive.

The lack of unity dated on 11/4/08. The special technical feature of Group 1 is mucosal vaccine adjuvant. The special technical feature does not make a contribution over the prior art as noted in McSorley et al. 2002 Journal of Immunology Vol. 169 pgs. 3914-3919. Therefore, unity of invention is lacking.

a) Examiner has withdrawn the species election of Species A flagellins and Species B of adjuvant.

b) Although Applicant has elected Sequences 5 and 6. The sequence election read on patentably distinct sequences. Each sequence is patentably distinct because SEQ ID NO: 5 is drawn to a nucleic acid and SEQ ID NO: 6 is drawn to an amino acid thus SEQ ID NOs: 5-6 are structurally different and further restriction is applied; therefore Examiner has withdrawn SEQ ID NO: 5.

c) Examiner has reconsidered the grouping of the inventions. It has been determined that Claim 6 is drawn to mucosal vaccine adjuvant which is an independent/patentably distinct product and must be placed in an independent group.

Thus Groups are as follows:

Group I claims 1-3 and 7 drawn to a mucosal vaccine adjuvants comprising bacterial flagellins as an active component

Group II claims 4-5 drawn to a method of manufacturing immunogen having adjuvanticity by flagellin.

Group III claim 6 drawn to Mucosal vaccine adjuvants comprising immunogens.

Claims 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species Group II (claims 4-5), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in 11/4/2008. Claims 1-3 and 7 are presently under examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 7, the phrase "so on" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al 1989 Proc. Natl Acad Science USA Vol. 86 pgs. 4726-4730.

Claims 1-2 and 7 are drawn to mucosal vaccine adjuvants comprising bacterial flagellins as an active component, wherein flagellins are originated from Salmonella typhimurium, wherein vaccine adjuvant are for recombinant protein vaccine (see pgs. 4726 column 2 last paragraph, 4727, 4729 (columns 1-2), and Figure 2-4.

#### ***Status of the Claims***

8. Claims 1-2 and 7 are rejected.

Claim 3 is objected to as being dependent upon a rejected base claim.

Claim 3 is allowable with elected sequence subjected matter of SEQ ID NO: 6 only.

No claims are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie

Examiner

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/Robert B Mondesi/

Supervisory Patent Examiner, Art

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